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December 9, 2004

Michael O. Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building (1101A)
1200 Pennsylvania Ave., NW
Washington, DC 20460



PETA

PEOPLE FOR THE ETHICAL
TREATMENT OF ANIMALS

HEADQUARTERS
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Re: Comments on the ACC's Test Plan for the Low 1,3-Butadiene C4 Category

Dear Administrator Leavitt:

The following comments on the American Chemistry Council's (ACC's) updated test plan for the low 1,3-butadiene C4 category are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

In our original comments on this test plan, we pointed to several reasons that the proposed combined repeat dose/reproduction/developmental study of 1-butene, a member of the category, was inappropriate. We stated:

Furthermore, we are concerned that these tests could be conducted under irrelevant conditions. Many of the similar compounds to 1- and 2-butene have been found to have no toxicological effect at concentrations above 2 to 3 percent in air. As pointed out in the high butadiene C4 plan, the atmosphere of tests conducted at these concentrations is explosive. At this point, the concern for acute toxic effects associated with combustion far outweigh any concern for the potential chronic effects from these gasses. Therefore, tests at these high concentrations are irrelevant and should not be conducted.

The results of the ACC's additional animal testing of the well characterized compound 1-butene were recently posted on the EPA website. The results were, as predicted, irrelevant to the regulation of butadiene and the protection of public health. No observed effects were reported at levels of 8,000 ppm of 1-butene in air for any of the endpoints, despite the study being conducted at half the concentration of the lower explosive limit of 16,000 ppm.

This testing typifies the thoughtless check-the-box approach to toxicology that has been a major concern of the animal protection community since the inception of the HPV program and which obviously carries over into the ICCA program. Despite abundant existing information, including a clear understanding of the toxicity mechanism of these compounds in humans, a common association of 1-butene with the highly regulated carcinogen 1,3-butadiene, documented difficulties in extrapolating the effects of these compounds from animals to humans, and previous animal testing on compounds containing up to 20% of this substance, the ACC insisted on conducting additional tests to demonstrate that a non-toxic substance is indeed non-toxic. In the process, the ACC condemned yet another 675 animals to suffering and death.

We are extremely disappointed that our previous comments were not addressed and that the ACC is so unconcerned with good science and animal welfare that it forged ahead with this testing.

Sincerely,

Jessica Sandler
Federal Agency Liaison